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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 1, 2000
(See OMB Statement on Page 2)

1. GENERIC TYPE OF DEVICE: Mobile Bearing Ankle Joint Replacement

2. ADVISORY PANEL: Orthopedic 21 CFR 888

3. IS DEVICE AN IMPLANT ?
[X] Yes [ ] No

4 INDICATIONS FOR USE PRESCRIBED, RECOMMENDED, OR SUGGESTED IN THE DEVICE'S LABELING THAT WERE CONSIDERED BY THE ADVISORY PANEL

The BUECHEL-PAPPAS™ Total Ankle Replacement is intended for reconstruction of painful and/or severely disabled ankle joints resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, or previously failed prosthesis. Viable malleoli, sufficient to provide medial-lateral stability, and viable ligaments to provide anterior-posterior stability as well as additional m-p stability. This device is intended for uncemented use.

5 IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General: Risks of any surgical procedure, and implantation of artificial joint replacements.

Specific Hazards to Health	Characteristics or Features of Device Associated with Hazard
a. Aseptic lossening of components	a. Constraint properties of the device
b. Wear-derbis induced Osteolysis	b. Congruency of the articulating surfaces
c. Sprains and Strains	c. Inversion-Eversion allowed by the device
d. Infection	d.

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY

Classification: Class II

Priority (Class II or III Only): High

7 IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

See sections III and IV

8 SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

See the attached document with Appendices for this information.

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE

See Form 3429, 11a. Fixation is a problem area where more than one solution might be suitable. Therefore, some form of special control might be needed to monitor this situation.

10. IF DEVICE IS IN CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

☐ a. Registration / Device Listing

☐ b. Premarket Notification

☐ c. Records and Reports

☐ d. Good Manufacturing Practice

11 EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES *(Components)* OR DEVICE MATERIALS *(Parts and Accessories)*

ASTM F67-95, Standard Specifications for Unalloyed Titanium for Surgical Implant Applications
ASTM F86-91, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.
ASTM F136-98, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications
ASTM F565-85(R1996), Standard Practice for Care and Handling of Orthopaedic Implants and Instruments
ASTM F648-96, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
ASTM F1044-95, Standard Test Method for Shear Testing of Porous Metal Coatings
ASTM F1108-97, Standard Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants
ASTM F1147-95, Standard Test Method for Tension Testing of Porous Metal Coatings
ASTM F1160-91, Standard Test Method for Constant Stress Amplitude Fatigue Testing of Porous Metal-Coated Metallic
Materials
ASTM F1580-95, Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants

12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0138)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W
Washington, DC 20201

(Please **DO NOT** RETURN this form to this address.)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 1, 2000
(See OMB Statement on Page 2)

PANEL MEMBER / PETITIONER: Endotec, Inc South Orange, NJ 07079

DATE: January 12, 2001

GENERIC TYPE OF DEVICE: Mobile Bearing Ankle Joint Replacement

CLASSIFICATION RECOMMENDATION: Class II

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☐ YES ☒ NO	Go to Item 2
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☒ YES ☐ NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES ☒ NO	Go to Item 4.
4 DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	☒ YES ☐ NO	If "Yes," go to Item 7. If "No," go to Item 5.
5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES ☐ NO	If "Yes," go to Item 7. If "No," Classify in Class I.
7 IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ? IF YES, CHECK THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II. ☒ Postmarket Surveillance ☒ Performance Standard(s) ☐ Patient Registries, ☐ Device Tracking ☐ Testing Guidelines ☐ Other (specify)	☒ YES ☐ NO	If "Yes," Classify in Class II If "No," Classify in Class III
8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD ☐ Low Priority ☒ Medium Priority ☐ High Priority ☐ Not Applicable		
9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?	☐ YES ☒ NO ☐ NOT Applicable	
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. ☐ Low Priority ☐ Medium Priority ☐ High Priority ☐ Not Applicable		

11a CAN THERE OTHERWISE BE REASONABLE ASSURANCE OF ITS SAFETY AND EFFECTIVENESS WITHOUT RESTRICTIONS ON ITS SALE, DISTRIBUTION OR USE, BECAUSE OF ANY POTENTIALITY FOR HARMFUL EFFECT OR THE COLLATERAL MEASURES NECESSARY FOR THE DEVICE'S USE ?	☒ YES ☐ NO	If "Yes," go to Item 12. If "No,", go to Item 11b.
11b. IDENTIFY THE NEEDED RESTRICTION(S) *(If Item 11a. was checked "NO ")* ☐ Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device ☐ Use only by persons with specific training or experience in its use ☐ Use only in certain facilities ☐ Other (Specify) _____		

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